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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,125	01/09/2004	Leslie Joe Dunaway	S-709-A	9374
2071 7590 12/08/2009 McGLINCHEY STAFFORD, PLLC Attn: IP Group 301 Main Street, 14th Floor BATON ROUGE, LA 70802			EXAMINER SIMMONS, CHRIS E	
			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			12/08/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/755,125

**Applicant(s)**

DUNAWAY, LESLIE JOE

**Examiner**

CHRIS E. SIMMONS

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-15, 18, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 16, 17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 8/13/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-6, 16, 17 and 19-24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (Biopharmaceutics & Drug Disposition (1997); (18)9:769-777).

The reference discloses the administration of 10 mg/day of montelukast to elderly patients (abstract; pg. 770). Twelve healthy young adults (panel A, four males and eight females) and twelve healthy elderly volunteers (panel B, eight males and four females) participated in this two-panel study. Mean age and body weight were 31.4 years ( $20 \pm 4.8$  years) and 66.6 kg ( $53.9 \pm 7.7$  kg), respectively, for young adults, and 69.4 years ( $65 \pm 7.3$  years) and 72.0 kg ( $57.1 \pm 8.6$  kg), respectively, for elderly subjects.

Accordingly, the latter comprise a discrete and separately identified patient population, and since in the prior art the same drug is administered in substantially the same amounts as the administration claimed instantly, and is specifically targeted to patients who will inevitably have some gray hair (the elderly), one would reasonably expect the prior art methods to inherently reduce graying in that patient population, whether explicitly recognized by the prior art or not.

### ***Response to Arguments***

Applicant relies on *Impax Laboratories, Inc. v. Aventis Pharm.* ("*Impax*") to argue that the claims are not anticipated by the prior art because it is not enabling. Applicant's arguments are not found to be persuasive because, in *Impax*, the prior patent's dosage guidelines were broad and generally without sufficient direction or guidance to prescribe treatment regimen. In the current case, however, the treatment regimen is specific, i.e., oral administration of 10 mg/d of montelukast to a specific group (i.e., elderly subjects) that inevitably has graying of hair. In *Impax*, the prior patent contains no working examples. There are working examples in the current case where the montelukast was actually administered the elderly subjects. In the current case, an ordinarily skilled artisan would not have needed to experiment unduly to gain possession of the invention because there is no need to first identify the specific therapeutic agent, montelukast, from amongst many others, as was the case in *Impax*. There is also no need for the artisan to identify specific amounts from a range of amounts like in *Impax*.

Applicant has not demonstrated that the prior art not enabling of the current invention. Applicant has argued that the prior art does not anticipated because there is no mention of treating graying of hair in the reference. The examiner submits, however, that the treating of graying of hair is an inherent outcome when the elderly population of subjects in the reference is administered 10 mg/d montelukast, i.e., an effective amount of montelukast for treatment of graying of hair as outlined in applicant's specification. Applicant also argues Zhao et al. teaches away from the current invention because it concludes that age plays little or no factor in determining dosage for montelukast, from

a pharmacokinetic point of view. The examiner submits that this statement in the reference would provide even more support for enablement since the ordinarily skilled artisan is not burdened with having to determine the proper dosage amount to administer the montelukast to the elderly subject. Accordingly, the argument that it teaches way is not persuasive.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRIS E. SIMMONS** whose telephone number is

(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./  
Examiner, Art Unit 1612  
/Gollamudi S Kishore/  
Primary Examiner, Art Unit 1612